



SiLibeads® Type P PHARMA RTS

Version: 2024-01-09 V8



Chemical/ Technical Parameter

Article: Glass Beads Borosilicate Type I Glass RTS (Ready to Sterilize)
 2.50 mm +/- 0.05 mm polished
 Article No. 55-02500-90RTS

Type of glass and applied regulations: Glass Beads are in accordance with the current versions of Pharmacopoeia Ph. Eur., USP and JP

Cleaning Process and applied regulations:

Water Quality
 Water for Injections (WFI) in accordance with the European Pharmacopoeia (Ph. Eur. Monograph 0169) and USP requirements.

Washer
 Washer meets GMP, GAMP and FDA 21 CFR Part 11 requirements.

Cleanroom
 Cleanroom conditions ISO 7 in accordance with DIN EN ISO 14644; Grade C (GMP).

Chemical Composition
 (main components in approx. weight %):

SiO ₂	81 %
B ₂ O ₃	13 %
Na ₂ O + K ₂ O	4 %
Al ₂ O ₃	2 %

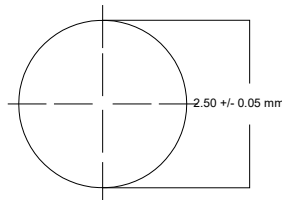
The heavy metal content (Pb, Cd, Hg, Cr-VI) is below 100 ppm

Chemical Resistance according to DIN methods:

Hydrolytic Resistance	HGA 1	(DIN ISO 720)
Acid Class	S1	(DIN 12116)
Alkaline Class	A2	(DIN ISO 695)

Density: 2.23 kg/dm³

Diameter: 2.50 mm Ø



Ø-Tolerance: +/- 0.05 mm

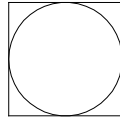
Surface roughness: $S_a < 0.111 \mu\text{m}$



SiLibeads® Type P PHARMA RTS

Version: 2024-01-09 V8

Sphericity: 0.1 mm



Ovality max.
0.1 mm

Quantity per kg: ≈ 54,800 pcs.

Inspection Strategy:

- ① 100 % Quality Control by a permanent validated optical inspection systems in clean room class 7 (EN ISO 14644) / Grade C (GMP)
- ② Final inspection by attributes in accordance with DIN ISO 2859-1

Criteria	inspection equipment	scope of inspection	AQL
Diameter: beads out of specification Tolerance 2.45 – 2.55 mm	Inspector (Measuring of diameter with calibrated Micrometer)	ISO 2859-1 Special Inspection S3 AQL table 2-A, Code H Amount: 50 pcs. per Lot-Number	MINOR AQL = 2.5 accepted 3 beads / rejected ≥ 4 beads
Wrong Beads: (e.g. coloured or matt beads)	Inspector (visual final control with lighted magnifier)	ISO 2859-1 General Inspect. Level II AQL table 2-A; Code Q Amount: 1,250 pcs. per Lot-Number	CRITICAL AQL = 0.010 accepted 0 beads / rejected ≥ 1 bead(s)
Broken beads (also half beads or broken twins)			CRITICAL AQL = 0.010 accepted 0 beads / rejected ≥ 1 bead(s)
Hair or hair-like fibers			CRITICAL AQL = 0.010 accepted 0 hair/fibres / rejected ≥ 1 hair/fibres
Cosmetical defects (dents, scratches, cracks, holes, cullets) + Foreign material (fixed spot) on the glass bead surface Size area ≥ 0.05 mm² (Diameter/Diagonal ≥ 0.25 mm)			MAJOR AQL = 0.40 accepted ≤ 10 beads / rejected ≥ 11 beads

Washing strategy and control strategy / Batch related verification of the purity of the glass beads:

The water, taken from the last washing step meets Ph. Eur. monograph 0169 "Water for Injection".

Washing process is successfully validated with regard to:

- Bacterial Endotoxin reduction of 3log units (Depyrogenation Process) according to Ph. Eur. Chapter 2.6.14 and USP-NF Chapter <85> and Chapter <1228>
- Bacterial Endotoxin detection limit according to Ph. Eur. Chapter 2.6.14 and USP-NF Chapter <85>
- Microbiological purity according to Ph. Eur. Chapter 2.6.12 (11.2); Ph. Eur. Chapter 2.6.13 (11.2) and DIN EN ISO 11737-1 (2021-10)
- Extraction of subvisible particles according to Ph. Eur. Chapter 2.9.19 (harmonised with USP-NF <788>)

Glass Beads for Medicinal Applications RTS
Technical Specification



The German spirit of quality since 1854



SiLibeads® Type P PHARMA RTS

Version: 2024-01-09 V8

Packaging:
<p>Standard packaging:</p> <ul style="list-style-type: none"> - 500g glass beads are packed in a sterilisable bag made with DuPont Tyvek® (size: 200x350mm) - This bag is covered by a second sterilisable bag made with DuPont Tyvek® (size: 320x450mm) - Max. 4 of these bags (“double” Tyvek bags) are packed in a plastic bag (produced under cleanroom conditions, size 450x660mm) - Use of a suitable cardboard box
The final packaging has to be specified with and approved by the customer and Sigmund Lindner.

Shelf Life:	From the date forth of washing/packaging Sigmund Lindner recommends a shelf life of maximum 3 years for the glass beads packed in sterilisable bags (packaging made with DuPont Tyvek®).
Recommended Storage Conditions:	<ul style="list-style-type: none"> - Keep in an environment of 15-30°C and 45-70% rel. humidity. - Protect from UV light and avoid outer storage. - Do not store near sources of heat or in indirect sunlight. - Protect original outer packaging from damage and dust. - Use FIFO method - Acclimatize products under processing conditions for 48 hours before use.

Issued by	Released by	Effective date
Simone Reichl Quality Assurance	Michael Dressler Head of Quality / Product Manager for Pharma and Food Applications	09.01.2024